

REMARKS

Prior to the non-final last Office Action, mailed August 4, 2008 in the present application, claims 8-54 were pending in the application. Of those claims, claims 8, 31 and 43 were independent claims.

In the non-final Office Action, mailed August 4, 2008, claims 8-54 were rejected as obvious under 35 U.S.C. §103(a) over FLETCHER-HAYNES et al. (2001/0034614), previously cited, in view of the newly cited and relied upon MORAND et al. (2002/0046054).

Applicants wish to thank Examiner Sheetal R. Rangrej and her Supervisory Examiner Jerry O'Connor for the interview with applicants' undersigned counsel at the Patent and Trademark Office on October 7, 2008.

The present invention is directed to a system (Claims 8-30), a computer readable medium (Claims 31-42) and a method (Claims 43-54) for managing an inventory of blood component collection soft goods to prevent the use of such soft goods which have been quarantined before they are used. Blood component collection soft goods typically come in a sealed package and provide the equipment for the collection of the blood or blood components from the donor, such as tubing, needles, containers and solutions needed for that purpose. See paragraphs 0392-3. Some of such

soft good packages may become quarantined before they are used (paragraphs 0105, 0268 and 0392-3) for any one of a number of possible reasons, such as previously opened or not sterile, becoming damaged or kinked, having passed the applicable use date or having been superseded by upgraded soft goods.

FLETCHER-HAYNES et al. discloses a computerized blood collection system which is designed to optimize and maximize the yield of desired blood components, such as platelets, plasma and red blood cells. See the Abstract and paragraphs 0162 and 0195. Disposable tubing such as may be utilized during the blood collection may also be identified and recorded (paragraph 0083), tubing size type and bag identifiers may be recorded (paragraph 0125) presumably to be able to determine which tubing was used with a given donor, and the type of tubing may be placed in the final report (paragraph 0166). However, there is no disclosure or suggestion whatsoever in FLETCHER-HAYNES et al. of inventorying any of the blood component collection soft goods or of quarantining such blood component collection soft goods either before or after use in the collection of blood from the donor. FLETCHER-HAYNES et al. is absolutely silent in those aspects.

Indeed, such failure of disclosure or suggestion in

FLETCHER-HAYNES et al. is admitted in the last Office Action, page 3, where it is stated:

Fletcher, however fails to expressly disclose a system for managing inventory of blood component collection soft goods and for preventing the use of quarantined soft goods, the system comprising:

(4) a system computer, wherein the system computer is in data communication with a system database having a blood component collection soft good inventory and quarantine information relative thereto, and said system computer processes said inventory and quarantine information prior to use of the blood component soft good; and

(5) the interface having a quarantine field for indicating that at least a portion of the blood component collection soft good inventory is quarantined based on the processing of the inventory and quarantined information prior to use of the blood component soft good.

Having admitted these critical failures of disclosure or teaching of FLETCHER-HAYNES et al., it is then stated in the Office Action at the top of page 4 that:

Nevertheless, these features are old and well known in the art, as evidenced by Morand.

In an attempt to justify this application of the newly cited MORAND et al. to modify the critically deficient FLETCHER-HAYNES et al., this statement is followed on page 4 of the Office Action by the following statement:

In particular, Morand discloses a system for managing inventory of blood component collection soft goods and for preventing the use of quarantined soft goods, the system

comprising:

(4) a system computer, wherein the system computer is in data communication with a system database having a blood component collection soft good inventory and quarantine information relative thereto, and said system computer processes said inventory and quarantine information prior to use of the blood component soft good **(Morand: par. [0057]-[0059])**; and

(5) the interface having a quarantine field for indicating that at least a portion of the blood component collection soft good inventory is quarantined based on the processing of the inventory and quarantined information prior to use of the blood component soft good **(Morand: par. [0062], [0067])**.

Quite to the contrary, MORAND et al. does not even relate to soft goods and/or the inventory and/or quarantine thereof. It is directed to the donors themselves. To quote the abstract of MORAND et al., its invention is directed to:

Systems consistent with the present invention provide a method for identifying and recruiting donors whose demographic characteristics, genomic and proteomic profile, and medical histories make them attractive candidates for clinical trials, drug target identification, and pharmacogenomic studies.

Thus, it is not surprising that there is absolutely no disclosure or suggestion in any of the cited paragraphs [0057] - [0059], [0062] or [0067] of soft goods, soft good inventory or soft good quarantine; i.e. the purported reasons for which those paragraphs were cited.

Paragraphs [0057] - [0059] of MORAND et al. state:

[0057] Based on the prospective donor's answers and test results, the individual is classified either as an accepted donor 130 or as a deferred donor 135. Medical history and clinical testing data along with the results of proteomic and genomic analyses of both accepted and deferred donors are combined to make the proteomics and genomics database 155.

[0058] The clinical trails database 160 comprises data collected from deferred donors. Optionally, the clinical trails database also may comprise data collected from accepted donors.

[0059] Data collected from donors are kept in perpetuity. As requested by an end-user and in compliance with an IRB-approved informed consent, donors are, from time to time, asked to supply additional and/or updated information. All such updates are incorporated into the permanent record of the donor.

Paragraph [0062] of MORAND et al. states:

[0062] A request to identify potential clinical trial subjects originates with an end-user 201 (See Fig. 2). The end-user provides desired subject characteristics 210 to the contractor 215. For example, the end-user may wish to identify individuals with specific pharmacogenomic characteristics, e.g., relating to a cytochrome P450. Based on those characteristics, the contractor formulates a query 220, which is designed to interrogate the clinical trials database 160 for subjects with the desired characteristics. The query is sent to Server A, which comprises the clinical trails database, over a communications network 230. Records in that database that satisfy the query are identified 240 and output as unique patient identifiers by Server A 250.

And paragraph [0067] of MORAND et al., the last of the

paragraphs which have been cited in the last Office Action for the purported disclosure of soft goods inventory and quarantine information, states:

[0067] Although the invention does not contemplate directly releasing data, other than names and contact information, supplied by individual donors to end-users, donors are, on occasion, asked for permission to release demographic information. Such demographic information is only released in confidence to end-users and without disclosing the identify of the individual(s) from whom that information was collected. Additionally, from time to time, and with donor consent, the results of donor testing for viruses, including, but not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV), are disclosed to end-users.

All of these paragraphs which were cited in the last Office Action in support of the rejection of the claims in the present application are directed to the donors to which the MORAND et al. invention is directed to. They are completely silent with regard to the purported purposes for which they were cited, i.e. to cure the critical failures of disclosure or teaching of FLETCHER-HAYNES et al. of soft goods, inventory of soft goods and/or quarantine of soft goods. **Indeed, applicants' undersigned counsel conducted a word search on MORAND et al. for the words "soft goods", "inventory" and "quarantine" and none of those words were found to exist anywhere in MORAND et al. in that search.**

In conclusion, neither FLETCHER-HAYNES et al. alone or

as modified by the disclosure of the newly cited MORAND et al. results in a system (claims 8-30), a computer readable medium (claims 31-42) or a method (claims 43-54) which include:

- Quarantining unsuitable blood component collection soft goods,
- Managing the inventory of unsuitable blood component collection soft goods,
- Providing a database to keep track of the inventory of unsuitable blood component collection soft goods,
- Preventing the use of unsuitable blood component collection soft goods, and/or
- Providing an interface with a quarantine field for indicating that a portion of the blood component collection soft goods is currently in quarantine.

In the last Office Action page 11, paragraph 33, it was stated:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Otworth et al. (U.S. Publication No. 2002/0059030) discloses a method and apparatus for the processing of remotely collected electronic information characterizing properties of biological entities.

and OTWORTH et al. was cited in a PTO-892 accompanying that Office Action.

It is not understood why OTWORTH et al. was again cited. It was already of record and was, in fact, the secondary reference that was relied upon to reject the claims in the present application in the Office Action mailed October 5, 2006.

Following applicant's Reply to that Office Action, OTWORTH et al. was dropped in the rejection of the claims in the next Office Action mailed March 21, 2007.

Paragraph [0035] of the specification has been amended herein to set forth more specifically some of the things that soft goods may include. Clear support for this amendment appears in originally filed dependent claims 10, 24 and 45.

Claim 8 has also been slightly amended to conform with the term "quarantine information" as set forth earlier in the claim. Applicants clearly do not consider this amendment to be substantive in any aspect, but to only be cosmetic in nature.

For the above reasons, it is respectfully submitted that all of the claims remaining in the present application, claims 8-54, are in condition for allowance. Accordingly, favorable reconsideration and allowance are

requested.

Respectfully submitted,

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